EXHIBIT 1

PATENTS

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Applicants:	David M. Center, et al.	**Examiner:**	B. Bunner
Serial No.:	09/368,630	**Art Unit:**	1647
Filed:	August 5, 1999	**Docket:**	12875

For: IL-16 ANTAGONIST PEPTIDES AND DNA ENCODING THE PEPTIDES

Assistant Commissioner for Patents
United States Patent and Trademark Office
Washington, D.C. 20231

DECLARATION OF DR. WILLIAM CRUIKSHANK UNDER 37 C.F.R. §1.132

Sir:

I, William Cruikshank, hereby declare as follows:

1. I am one of the co-inventors named in the above-identified application. I hold a Bachelor of Science (B.S.) Degree in Biology and a Doctorate Degree in Biochemistry. I am currently employed by Boston University School of Medicine. I have been conducting research in the field of Immunology since 1978, and have authored 97 publications. A true and correct copy of my curriculum vitae is attached hereto as **Exhibit A.**

2. I have reviewed the above-identified application ("the '630 application) and I am familiar with the subject matter therein. I have been asked to review and comment on issues raised by the Examiner in the Office Action dated June 6, 2002.

3. It is my understanding that the Examiner acknowledges that the specification is enabling for an isolated IL-16 antagonist peptide consisting of the amino acid sequence of SEQ

ID NOs: 2, 5, 6, 17 and 24, and for a composition comprising such a peptide and a pharmaceutically acceptable carrier. However, the Examiner contends that the specification does not reasonably provide enablement for all IL-16 antagonist peptides as claimed in the present application, including an IL-16 antagonist peptide consisting of an amino acid sequence as set forth in any one of SEQ ID NOs: 3-4, 9-11, 13-16, 18-23, 25-32 or 34-38, or for a composition comprising such an IL-16 antagonist peptide and a pharmaceutically acceptable carrier.

4. The Examiner recognizes that the specification provides working examples which demonstrate that the isolated antagonist peptides of SEQ ID NOs: 2, 5, 6, 17 and 24 inhibit IL-16 stimulated human T lymphocyte cell migration (see, for example, pages 34-35). However, the Examiner contends that the specification does not provide any working examples which demonstrate that the isolated peptides of SEQ ID NOs: 3-4, 9-11, 13-16, 18-23, 25-32 and 34-38 are capable of inhibiting IL-16 mediated T lymphocyte migration. The Examiner is of the opinion that, in the absence of supporting evidence, the assumption that the peptides of SEQ ID NOs: 3-4, 9-11, 13-16, 18-23, 25-32 and 34-38 have biological activities similar to the antagonist peptides of SEQ ID NOs: 2, 5, 6, 17 and 24, cannot be accepted.

5. To demonstrate the functionality of the claimed IL-16 antagonist peptides, eight (8) peptides, which consist of a sequence as set forth in SEQ ID NO: 25-28, 32, 34-35 and 37, respectively, were examined for the ability to block IL-16 induced chemoattraction, essentially following the procedures described at page 32 of the specification of the '630 application. 15 cells/hpf under control conditions were counted. IL-16 (10^{-10}M) alone induced 205%+/-12 migration of human T cells. Peptides were used at 5ug/ml and added to IL-16 prior to migration assay. The data is expressed as a % of control cell migration in **Table 1 (Exhibit B)**. Migration

above 135% is statistically significant and a 20% reduction or greater is statistically significant at 5% confidence level.

6. The peptides were also assayed for the ability to block a mixed lymphocyte reaction, essentially following the procedures described at page 33 of the specification of the '630 application. Peptides were used at 5ug/ml and added to responder cells at the same time as stimulator cells. Peptides 7-8 were tested separately from peptides 1-6. The Results were summarized in **Table 2 (Exhibit B)**.

7. The data presented in Table 1 and Table 2 demonstrate that the peptides consisting of a sequence as set forth in SEQ ID NO: 25-28, 32, 34-35 and 37, respectively, effectively antagonize the biological effects of IL-16, as determined by the IL-16 induced chemoattraction assay and the MLR assay.

8. I declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and that those statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issuing thereon.

Signature: _____

Dated: November 6, 2002